

Mrs. Sue N. Hanselman
4772 Edgeworth Drive
Manlius, New York 13104
(315) 682-6498 dlhansel@mailbox.syr.edu

May 14, 1999

To: Food and Drug Administration
Dockets and Management Branch (HFA-305)

2088 '99 MAY 18 AM 1:35

RE: Docket No. 98N-1265

This letter has been sent to my elected representatives:

I am very disturbed by the current draft of the memorandum of understanding (MOU) dealing with the practice of pharmacy compounding (docket No. 98N-1265). I strongly urge you to amend this MOU to ensure that consumers such as myself are guaranteed the right to obtain compounded medications, necessary for the treatment of medical conditions, from compounding pharmacies of their choice

In my early 40's, my medical condition necessitated the removal of both ovaries. My doctor then prescribed Hormone Replacement Therapy. I began taking the prescribed synthetic hormones, manufactured by the pharmaceutical companies, but had adverse reaction to them. I began extensive research to find alternatives to the dosages or types (i.e., synthetics) of hormones which had been prescribed. The more I learned, the more uncomfortable I became with the side-effects of these Hormone Replacement Therapy drugs and the cancer risks associated with their long-term use.

My research led me to discover the advantages of using a compounding pharmacy that would formulate natural estrogens in ratios more closely approximating the ratio naturally found in a woman's body. My physician agreed and readily prescribed an estrogen/progesterone formulation. I have found that this type and ratio of hormone does not result in the side effects associated with the synthetic estrogens, nor does it carry the high cancer risk of the synthetic hormone products of the main-line pharmaceutical companies. Indeed, there is some evidence that the compounded estrogen/progesterone I am using may even reduce my long term risk of cancer!

As you may know, there are relatively few compounding pharmacies. When I inquired of my NYS Empire Plan insurance carrier about coverage of hormone products from a compounding pharmacy, they put me in touch with Women's International Pharmacy of Madison, Wisconsin.

Now, it appears that pending legislation (docket No. 98N-1265) could jeopardize the inter-state distribution of my compounded prescription medication. This is very disturbing!

I request that you represent my interest, and the interests of others like me, by amending the MOU in question, to assure that compounded prescription medications will always be available and able to be purchased from pharmacies of choice regardless of their location.

I thank you for giving this your attention and am anxious to have your response to this issue.

Yours truly,

Sue N. Hanselman

Sue N. Hanselman

98N-1265

C 2292

98N-1265

*Dr. & Mrs. David L. Hanselman
4772 Edgeworth Dr.
Manlius, NY 13104*



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Ln. Rm 1061
Rockville, MD 20857-0003

20857/0003

